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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

PADMANABHAN, KARTIC

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 11/04/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,016

Applicant(s)

LYLES, MARK B.

Examiner

Kartic Padmanabhan

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 5 is acknowledged. The traversal is on the ground(s) that a search of both groups would not be burdensome. This is not found persuasive for reasons set forth in the restriction requirement mailed on August 2, 2002.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78(a)(2) and (a)(5)).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 8 recites the limitation "the mean pore diameter". There is insufficient antecedent basis for this limitation in the claim.

6. Claim 9 recites the limitation "the density". There is insufficient antecedent basis for this limitation in the claim.

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7. Claim 10 recites the limitation "the exposed surface". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Yves et al. (US Pat. 5,460,940). The reference discloses methods and cards for detecting antigens or antibodies. The method of the reference comprises the use of inert porous particles. The particles may be made of porous glass or porous silica (abstract). The reference also discloses that the reactions may be carried out in microtiter plates made of glass or plastic.

10. Claims 1, 8, 10, 11, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Schoning et al. (US Pat. 5,874,047). The reference discloses silicon based biosensors comprising porous silicon. The mean pore diameter is 1 nm – 100 um. The porous layer is covered by a layer of silicon dioxide (abstract). Biological structures such as enzymes, protein, antibodies, and others can be crosslinked in the porous layer.

11. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kreuwel (WO 98/20322). The reference discloses a diagnostic test device for bodily fluids comprising a porous carrier that may be made of silica.

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Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 1 and 4-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lyles et al. (WO 96/24631).

The reference discloses or teaches dental materials comprising from about 1% to 50% by weight alumina, 50% to 90% by weight silica, and 1% to 5% by weight boron. The mean pore diameter of the material is greater than 10 microns (page 20). The density of the material may be up to 62 pounds per cubic foot (page 5).

If the preamble of the claim is not given patentable weight, as is generally the case, the reference anticipates the claims because it discloses all the elements of the claims to which it was applied. However, if the preamble is given weight, the reference renders the claimed invention *prima facie* obvious. Silica is well known in the art in diagnostic systems. For example, glass microscopic slides, which are considered to be diagnostic, are often made of silica. In addition,

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as evidenced by US Pat. 6,100,966 above, porous silica carriers are known to be used in test devices. As such, one would have had a reasonable expectation of success in using the composition of Lyles et al. for diagnostic purposes, especially when considering that silica, alumina, and boron all have conducting properties.

15. Claim 2 rejected under 35 U.S.C. 103(a) as being unpatentable over Yves et al. (US Pat. 5,460,940) in view of Schoning et al. (US Pat. 5,874,047).

Yves et al. and Schoning et al. teach methods and sensors for detection, as previously discussed. However, the references do not teach a microtiter plate made of porous silica.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use porous silica with the microtiter plate of Yves et al. because Schoning et al. teach that a three dimensional structure of porous silicon improves anchorage of sensor active material. In addition, Yves et al. state the microtiter plate material is not critical.

16. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoning et al. (US Pat. 5,874,047) or Lyles et al. (WO 96/24631) in view of Beattie (US Pat. 5,843,767).

Schoning et al. and Lyles et al. teach devices or compositions, as previously discussed. However, the references do not teach immobilization of oligonucleotides or DNA.

Beattie teaches attachment of oligonucleotides and DNA to silicon dioxide (silica).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize oligonucleotides or DNA as taught by Beattie with the devices and composition of Schoning et al. or Lyles et al. because Beattie teaches that these molecules can be successfully attached to surfaces comprising silica.

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17. Claims 13, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoning et al. (US Pat. 5,874,047) or Lyles et al. (WO 96/24631) in view of Shivashankar et al. (US Pat. 6,139,831).

Schoning et al. and Lyles et al. teach devices or compositions, as previously discussed. However, the references do not teach immobilization of DNA or RNA.

Shivashankar et al. teach the immobilization of DNA, RNA, and carbohydrates to silica.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize DNA, RNA, or carbohydrates as taught by Shivashankar et al. with the devices and composition of Schoning et al. or Lyles et al. because Shivashankar et al. teach that these molecules can be successfully attached to surfaces comprising silica.

18. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schoning et al. (US Pat. 5,874,047) or Lyles et al. (WO 96/24631) in view of Blake et al. (US Pat. 5,439,792).

Schoning et al. and Lyles et al. teach devices or compositions, as previously discussed. However, the references do not teach immobilization of peptides.

Blake et al. teach attachment of peptides to solid phases that may comprise silica.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to immobilize peptides as taught by Blake et al. with the devices and composition of Schoning et al. or Lyles et al. because Blake et al. teach that peptides can be successfully attached to surfaces comprising silica.

Conclusion

Claims 1-18 are rejected.

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References: Breitbarth and Duran et al. are cited as art of interest for teaching types of substrates and/or methods for attaching biomolecules to the substrates.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509.


The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

October 29, 2002


LONG V. LE
SUPERVISORY PATENT EXAMINER
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11/01/02